IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

MERCK & CO., Inc. Plaintiff, v. RANBAXY INC. and RANBAXY LABORATORIES LIMITED, Defendant.	)	C.A. No. 07-229 (GMS)
RANBAXY INC. and RANBAXY LABORATORIES LIMITED, Counterclaim Plaintiff, v. MERCK & CO., Inc. Counterclaim Defendant.	)	

ANSWER AND COUNTERCLAIMS OF DEFENDANTS RANBAXY INC. AND RANBAXY LABORATORIES LIMITED

Defendants Ranbaxy Inc. and Ranbaxy Laboratories Limited (collectively "Ranbaxy") hereby answer the Complaint for Patent Infringement of Plaintiff Merck & Co., Inc. ("Merck") as follows:

PARTIES

1. Ranbaxy admits the allegations of paragraph 1 of the Complaint.

2. Ranbaxy admits that Ranbaxy Inc. is a corporation organized and existing under the laws of the state of Delaware, has a principal place of business at 600 College Road East, Princeton, New Jersey, 08540, and conducts business in the state of Delaware.

Ranbaxy admits that Ranbaxy Pharmaceuticals Inc. is engaged in the marketing and sale of pharmaceutical products in the United States and that it conducts business in the state of Delaware. Ranbaxy denies all other allegations in Paragraph 2 of the Complaint.

3. Ranbaxy admits that Ranbaxy Laboratories Limited is a corporation organized and existing under the laws of India, having a principal place of business at Gurgaon (Haryana) India. Ranbaxy admits that Ranbaxy Inc. is a wholly owned subsidiary of Ranbaxy Laboratories Limited. Ranbaxy Laboratories Limited develops manufactures, markets and sells drug products in India and, in cooperation with Ranbaxy Inc. and Ranbaxy Pharmaceuticals Inc., conducts business in the United States and in the state of Delaware. Ranbaxy denies all other allegations in Paragraph 3 of the Complaint.

4. Ranbaxy admits that Ranbaxy Inc. and Ranbaxy Laboratories Limited have submitted an Abbreviated New Drug Application ("ANDA") directed to imipenem/cilastatin sodium, and associated drug master file(s) seeking approval to engage in the commercial manufacture, use, offer for sale and sale of injectable products comprising imipenem and cilastatin sodium. Ranbaxy denies all other allegations in Paragraph 4 of the Complaint.

JURISDICTION AND VENUE

5. Paragraph 5 of the Complaint states legal conclusions to which no response is required. To the extent a response is required, Ranbaxy admits that this action for patent infringement arises under the patent laws of the United States, and for declaratory relief under 28 U.S.C. §§ 2201 and 2202 and under the patent laws of the United States. Ranbaxy admits that this Court has jurisdiction over the subject matter of

Merck's infringement counts pursuant to 28 U.S.C. §§ 1331 and 1338(a) and Merck's declaratory judgment counts pursuant 28 U.S.C. §§ 2201 and 2202.

6. Paragraph 6 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy admits that venue is proper in this District for this action only.

MERCK'S PATENT

7. Ranbaxy admits that U.S. Patent No. 5,147,868 is entitled "Thienamycin Renal Peptidase Inhibitors," bears an issue date from the United States Patent and Trademark Office of September 15, 1992, lists Merck & Co., Inc. as the assignee, and lists as inventors Donald W. Graham, Edward F. Rogers and Frederick M. Kahan. As presently understood, Ranbaxy also admits that one or more claims of the '868 patent appear to cover the compounds cilastatin and cilastatin sodium. Ranbaxy lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 7 of the Complaint and therefore denies the same.

8. Based on Merck's representations, Ranbaxy admits the allegations of paragraph 8 of the Complaint.

9. Ranbaxy is without knowledge sufficient to form a belief in the truth of the allegations of Paragraph 9 of the Complaint, and therefore denies the same.

DEFENDANTS' ACTIONS

10. Ranbaxy admits that it filed an ANDA and associated drug master file(s), seeking approval to engage in the commercial manufacture, use and sale of injectable products comprising imipenem and cilastatin sodium ("proposed injectable products"). Ranbaxy denies the remaining allegations of Paragraph 10 of the Complaint.

11. Ranbaxy admits that by letter of January 22, 2007, it notified Merck of its ANDA filing; that its proposed injectable products would not infringe any valid claim of the '868 patent, and that Ranbaxy planned to begin marketing its proposed injectable products immediately upon approval. Ranbaxy admits that it requested from Merck a Covenant Not to Sue, which Merck denied. Ranbaxy denies the remaining allegations of Paragraph 11 of the Complaint.

12. Ranbaxy admits that it has complied with the applicable regulatory requirements in filing its ANDA, and that it has developed and carried out testing on the proposed injectable products that it has developed. Ranbaxy Laboratories Limited manufactures a composition containing imipenem and cilastatin sodium in India and markets and sells that composition in India and Peru. Ranbaxy admits that it is prepared to import its proposed injectable products into the United States and that it has the capacity to manufacture and market its proposed injectable products immediately upon approval of its ANDA. Ranbaxy denies the remaining allegations of Paragraph 12 of the Complaint.

COUNT 1- DECLARATORY JUDGMENT

13. Ranbaxy repeats and realleges its responses to the allegations in paragraphs 1-12 of the Complaint as though fully set forth herein.

14. Ranbaxy admits engaging in activities in preparation for approval of its ANDA, but denies that the manufacture, use, offer for sale of sale of its proposed injectable products would constitute infringement of the '868 patent.

15. To the extent the allegations of Paragraph 15 of the Complaint are understood, Ranbaxy admits that it continues to seek FDA approval of its ANDA, that it

plans to market its proposed injectable products immediately upon FDA approval of its ANDA, and that it notified Merck of its good-faith belief as to why no valid claim of the '868 would be infringed by Ranbaxy's manufacture, use, offer for sale and sale of its propose injectable products. Ranbaxy denies the remaining allegations of Paragraph 15 of the Complaint.

16. Ranbaxy denies the allegations of Paragraph 16 of the Complaint.

17. By reason of Ranbaxy's having filed its ANDA, Merck's refusal to grant Ranbaxy a covenant not sue, and Merck's having filed suit against Ranbaxy, Ranbaxy admits that an actual controversy exists between Merck and Ranbaxy with respect to the noninfringement, invalidity and unenforceability of the '868 patent.

18. Ranbaxy denies the allegations of Paragraph 18 of the Complaint.

19. Ranbaxy denies the allegations of Paragraph 19 of the Complaint.

20. Ranbaxy denies the allegations of Paragraph 20 of the Complaint.

21. Ranbaxy admits that, through its own investigation, it has learned of the '868 patent but denies the remaining allegations of Paragraph 21 that of the Complaint.

22. Ranbaxy denies the allegations of Paragraph 22 of the Complaint.

23. Ranbaxy denies the allegations of Paragraph 23 of the Complaint.

24. Ranbaxy denies the allegations of Paragraph 24 of the Complaint.

COUNT II -- PATENT INFRINGEMENT

25. Ranbaxy repeats and realleges its responses to the allegations in paragraphs 1-24 of the Complaint as though fully set forth herein.

26. Ranbaxy admits that it has filed an ANDA under Section 505(j) of the Federal Food Drug and Cosmetic Act, 21 U.S.C. §355(j) for its proposed injectable products. Ranbaxy denies the remaining allegations of Paragraph 26 of the Complaint.

27. Ranbaxy admits that it seeks approval of its ANDA and the proposed injectable products described therein, but denies that its proposed injectable products would infringe any valid claim of the '868 patent. Ranbaxy denies the remaining allegations of Paragraph 27 of the Complaint.

28. Ranbaxy denies the allegations of Paragraph 28 of the Complaint.

29. Ranbaxy denies the allegations of Paragraph 29 of the Complaint.

30. Ranbaxy admits that, through its own investigation, it has learned of the '868 patent but denies the remaining allegations of Paragraph 30 of the Complaint.

31. Ranbaxy denies the allegations of Paragraph 31 of the Complaint.

32. Ranbaxy denies the allegations of Paragraph 32 of the Complaint.

33. Ranbaxy denies the allegations of Paragraph 33 of the Complaint.

MERCK'S PRAYER FOR RELIEF

Ranbaxy denies that Merck is entitled to any aspect of the judgment it seeks.

DEFENSES

Ranbaxy asserts the following defenses, reserving the right to supplement or amend these defenses as discovery proceeds.

FIRST DEFENSE
(Non-infringement of '868 Patent)

34. Ranbaxy does not infringe, has not infringed, and does not and has not induced infringement or contributed to infringement of the '868 patent-in-suit, either literally or under the doctrine of equivalents.

SECOND DEFENSE
(Estoppel/Disclaimer of Claim Scope)

35. Merck is estopped from asserting any scope for one or more of the claims of the '868 patent which would cover Ranbaxy's proposed injectable products because of amendments, representations, assertions, disclaimers and/or admissions made during the course of proceedings in the United States Patent and Trademark Office ("PTO") during prosecution of the applications leading to the issuance of the '868 patent ("the '868 patent applications") and during the prosecution of all applications in the family beginning with the filing of Application Serial No. 05/927,213 ("the '213 family applications") and other Merck patents/applications and foreign counterparts of any such applications or patents, including but not limited to, prosecution disclaimer.

THIRD DEFENSE
(Estoppel)

36. To the extent not encompassed by Ranbaxy's Second Defense, Merck is estopped from construing the claims of the '868 patent to cover and include Ranbaxy's proposed injectable product.

FOURTH DEFENSE
(Invalidity of '868 Patent)

37. Each and every claim of the '868 patent is invalid for failure to meet the statutory requirements of Title 35 of the United States Code, including, but not limited to, the failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112.

FIFTH DEFENSE
(Invalidity of '868 Patent)

38. Each and every claim of the '868 patent is invalid for failing to meet judicially-created requirements for patentability and enforceability of patents, including but not limited to, obviousness-type double patenting based on U.S. Patent No. 4,539,208.

SIXTH DEFENSE
(Prosecution Laches)

39. Merck's claim for patent infringement and prayers for relief are barred, in whole or in part, because the equitable doctrine of prosecution laches renders the '868 patent unenforceable.

SEVENTH DEFENSE
(Limitation on Damages)

40. Merck is barred under 35 U.S.C. § 287 from recovering damages for any alleged act of infringement by Ranbaxy that occurred prior to actual notice of alleged infringement of the '868 patent from Merck.

RANBAXY'S COUNTERCLAIMS

Defendants/Counterclaimants Ranbaxy Inc. and Ranbaxy Laboratories Limited (collectively "Ranbaxy") hereby allege the following counterclaims against Plaintiff/Counterdefendant Merck & Co., Inc. ("Merck"), for declaratory judgment that U.S. Patent No. 5,147,868 is invalid, unenforceable, and/or not infringed by the proposed injectable products comprising imipenem and cilastatin sodium ("proposed injectable product") in Ranbaxy's Abbreviated New Drug Application ("ANDA") and associated drug master file(s).

PARTIES, JURISDICTION AND VENUE

41. Ranbaxy Inc. is a corporation organized and existing under the laws of the state of Delaware, and has a principal place of business at 600 College Road East, Princeton, New Jersey, 08540. Ranbaxy Laboratories Limited is a corporation organized and existing under the laws of India, having a principal place of business in Gurgaon (Haryana) India.

42. On information and belief, Merck is a corporation incorporated under the laws of New Jersey with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey.

43. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 1367(a), 2201 and 2202, and 35 U.S.C. § 1, et seq.

44. Merck has submitted to the personal jurisdiction of this Court.

45. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400 and because this suit was filed in this district by Merck.

THE CONTROVERSY

46. This is an action based on an actual controversy between Ranbaxy and Merck concerning the invalidity and/or noninfringement of the '868 patent-in-suit, and Ranbaxy's right to continue to seek approval of its ANDA for its proposed injectable products, and upon approval by the FDA, to manufacture use, sell and offer to sell and import into the United States its proposed injectable products.

47. United States Patent No. 5,147,868 is entitled "Thienamycin Renal Peptidase Inhibitors," bears an issue date from the United States Patent and Trademark

Office of September 15, 1992, lists Merck & Co., Inc. as the assignee, and lists as inventors Donald W. Graham, Edward F. Rogers and Frederick M. Kahan.

48. Merck has represented that one or more claims of the '868 patent appear to cover the compounds cilastatin and cilastatin sodium. Merck has represented that it currently sells PRIMAXIN® I.M., which is an injectable suspension containing imipenem and cilastatin sodium, and PRIMAXIN® I.V., which is an injection containing imipenem and cilastatin sodium.

49. Ranbaxy has submitted, and is continuing to seek FDA approval of, an ANDA directed to products containing imipenem/cilastatin sodium, and approval to engage in the commercial manufacture, use, offer for sale, sale, and importation into the United States, its proposed injectable products under that ANDA, which Merck alleges infringes the '868 patent-in-suit.

50. By letter of January 22, 2007, Ranbaxy informed Merck that it had submitted to FDA its ANDA directed to its proposed injectable product, and stated that the manufacture, use, offer for sale or sale of its proposed injectable products would not infringe any valid claim of Merck's '868 patent.

51. Ranbaxy also informed Merck that it planned to begin marketing of its proposed injectable products immediately upon FDA approval of its ANDA. Ranbaxy sought from Merck a covenant not to sue on the '868 patent, and provided to Merck an offer of confidential access to its ANDA and its DMF(s) for the purpose of determining whether to grant Ranbaxy a covenant not to sue. Merck did not covenant not to sue Ranbaxy, and filed this suit April 30, 2007.

52. Ranbaxy has undertaken substantial efforts in developing and seeking approval for its imipenem/cilastatin proposed injectable products set forth in its ANDA.

53. In view of the foregoing, an actual justiciable controversy exists by virtue of Ranbaxy's notification to Merck of its ANDA filing, Ranbaxy's request for a covenant not to be sued on the '868 patent, and Merck's subsequent filing of the present suit as to Ranbaxy's right to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and importation into the United States, its proposed injectable products described in its ANDA.

COUNTERCLAIM I
(Noninfringement of '868 Patent)

54. Ranbaxy repeats and realleges paragraphs 41-53 above as if fully set forth herein.

55. Ranbaxy has not manufactured, used, sold, or offered for sale in the United States, or imported into the United States, any products that infringe any valid claim of the '868 patent, either literally or under the doctrine of equivalents.

56. Ranbaxy's proposed injectable products do not infringe any valid claim of the '868 patent, either literally or under the doctrine of equivalents and Ranbaxy does not and has not induced infringement or contributed to infringement of any valid claim of the '868 patent, either literally or under the doctrine of equivalents.

57. Merck is estopped from asserting any scope for one or more of the claims of the '868 patent which would cover Ranbaxy's proposed injectable products because of amendments, representations, assertions, disclaimers and/or admissions made during the course of proceedings in the United States Patent and Trademark Office ("PTO") during prosecution of the applications leading to the issuance of the '868 patent applications and

during the prosecution of all applications in the family beginning with the filing of Application Serial No. 05/927,213 and other Merck patents/applications and foreign counterparts of any such applications or patents, including but not limited to, prosecution disclaimer.

COUNTERCLAIM II
(Invalidity of '868 Patent)

58. Ranbaxy repeats and realleges paragraphs 41-57 above as if fully set forth herein.

59. Each and every claim of the '868 patent is invalid for failure to meet the statutory requirements of Title 35 of the United States Code, including, but not limited to, the failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112.

60. Each and every claim of the '868 patent is invalid for failing to meet judicially-created requirements for patentability and enforceability of patents, including but not limited to, obviousness-type double patenting based on U.S. Patent No. 4,539,208.

COUNTERCLAIM III
(Unenforceability)

61. Ranbaxy repeats and realleges paragraphs 41-60 above as if fully set forth herein.

62. Merck unfairly and inequitably filed multiple continuation applications over a long period of time. Because Merck failed to timely prosecute the '868 patent, the '868 patent is unenforceable due to prosecution laches.

DEMAND FOR JUDGMENT

WHEREFORE, Ranbaxy prays for the following relief:

(1) That any and all relief requested by Merck, as set forth in the Prayer of Relief of the Complaint, be denied and that the Complaint be dismissed with prejudice;

(2) That a judgment be entered declaring that Ranbaxy has not and does not infringe any claim of U.S. Patent No. 5,147,868;

(3) That a judgment be entered declaring all claims of U.S. Patent No. 5,147,868 invalid and/or unenforceable;

(4) That Ranbaxy has a lawful right to seek and obtain FDA approval of its ANDA for its imipenem/cilastatin sodium injectable products, and that based on the noninfringement, invalidity and/or unenforceability of U.S. Patent No. 5,147,868, Ranbaxy has a right to import, manufacture, use, offer for sale and sell its proposed imipenem/cilastatin sodium injectable products once approved by FDA;

(5) That Merck, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them, be preliminarily and permanently enjoined from threatening or initiating further infringement litigation against Ranbaxy or any of its customers, dealers or suppliers, or any prospective sellers, dealers, distributors or customers of Ranbaxy, or charging any of them either orally or in writing with infringement of U.S. Patent No. 5,147,868;

(6) That a judgment be entered declaring this case to be exceptional within the meaning of 35 U.S.C. §285 and that Ranbaxy is entitled to recover its reasonable attorneys' fees upon prevailing in this action;

(7) That Ranbaxy be awarded costs, attorneys' fees and other relief, both legal and equitable, to which they may be justly entitled; and

(8) That Ranbaxy be awarded such other relief as this Court deems just and proper.

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Dated: June 21, 2007

UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on June 21, 2007, I electronically filed the foregoing document with the Clerk of Court using CM/ECF and caused the same to be served on the defendant at the addresses and in the manner indicated below:

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I hereby certify that on June 21, 2007, the foregoing document was sent to the following non-registered participants in the manner indicated:

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